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37492 7590 08/10/2007 CELERA DIAGNOSTICS, LLC 1401 HARBOR DAY PARKWAY ALAMEDA, CA 94502			EXAMINER KAPUSHOC, STEPHEN THOMAS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,471

Applicant(s)

CARGILL ET AL.

Examiner

Stephen Kapushoc

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 27-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 27-65 is/are rejected.
- 7) ☒ Claim(s) 27,29,37,39,47,49,57 and 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/29/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, and 27-65 are pending and examined on the merits.
Claims 2-26 are cancelled.

This Office Action is in reply to Applicants' correspondence of 05/29/2007.
Claim(s) 2-26 is/are cancelled; no claim(s) is/are withdrawn; claim(s) 27-65 has/have been newly added; claim(s) 1 has/have been amended.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put the application in condition for allowance. Any new grounds of rejection presented in this Office Action are necessitated by Applicants' amendments. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is made **FINAL**.

1. Please note, the text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Claim Objection

2. The objection of claims for the recitation of non-elected SEQ ID NOs is withdrawn in light of the amendments to the claims specifying the elected SEQ ID NO: 36,673 and nucleic acid sequences comprising or contained in SEQ ID NO: 36,673.

New Claim Objections

3. Claims 27, 37, 47, and 57 are objected to for the specific recitation of non-elected subject matter. In the Election of 09/26/2006 Applicants elected for the analysis of claims as they are drawn to the specific autoimmune disease rheumatoid arthritis. Prior to allowance of any claims, the claims will be required to be amended to remove recitations of any specific non-elected diseases.

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4. Claims 29, 39, 49, and 59 are objected to over recitation of the phrase 'the genomic sequence of PTPN22 gene', where the phrase 'the genomic sequence of the PTPN22 gene' is correct. Appropriate correction is required.

Withdrawn Claim Rejection - 35 USC § 112 2nd ¶ - Indefiniteness

The rejection of claims 23 and 24 n 35 USC 112 2nd ¶ is withdrawn in light of the cancellation of claims 23 and 24.

New Claim Rejection - 35 USC § 112 2nd ¶ - Indefiniteness

5. Claims 1 and 27-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 27-45 are unclear over recitation of the phrase 'detecting the presence of a single nucleotide polymorphism' (as recited in claims 1 and 36) with regard to detecting a SNP. Because a 'SNP' is position with variable nucleotide content within a population of nucleotide sequences, and the claims do not require the detection of specific nucleotide content, it is unclear what is required to perform the claimed method. Note that this rejection does not apply to claims 46-65, where the independent claims 46 and 56 specify detecting the presence of specific nucleotide content at position 101 of SEQ ID NO: 36,673.

Claim 32 is unclear over recitation of the phrase 'said biological sample' because there is not proper antecedent basis for any 'biological sample' in claim 32, or claims 28 or 1 from which claim 32 depends. See MPEP 2173.05(e).

New Claim Rejection - 35 USC § 112 1st - Written Description, New Matter

6. Claims 1, 29-31, 33-36, 39-46, 39-56, and 59-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

1, 29-31, 33-36, 39-46, 39-56, and 59-65 are drawn to methods for identifying a human having an altered risk for developing 'an autoantibody-positive autoimmune disease'. Neither the specification nor claims as originally filed contemplate methods for the identification of risk of the specific subgenus of 'autoantibody-positive autoimmune' diseases. The original specification and claims are drawn to the genus of diseases of 'autoimmune diseases', and while that large genus encompasses 'autoantibody-positive autoimmune' diseases, the specification provides no specific contemplation of nucleotide content with the specific 'autoantibody-positive' subgenus. And while the specification provides examples of several particular autoimmune disease that may be either be autoantibody positive or negative, and teaches some associations with particular autoantibody-positive autoimmune diseases (e.g. RF(+) RA), these particular

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examples do not serve to provide support for the large subgenus of 'autoantibody-positive autoimmune' diseases. Note that this rejection does not apply to claims 27, 28, 32, 37, 38, 47, 48, 57, and 58, which specify particular diseases for which there is basis in the specification.

Maintained Claim Rejection - 35 USC § 112 1st - Written Description

7. Claims 1 and 27-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-111 (also available at www.uspto.gov <<http://www.uspto.gov>>).

The rejected claims are drawn to methods comprising detecting a single nucleotide polymorphism (SNP) at position 101 of SEQ ID NO: 36,673, wherein the presence of the SNP is correlated with an altered or increased risk for developing and autoantibody-positive autoimmune disease. Note that the rejection does not apply to claims 46-65 which specify a particular nucleotide content at position 101 of SEQ ID NO: 36,673.

The claims are thus broadly drawn to methods comprising the detection of a variety of nucleic acids, including any SNP at position 101 SEQ ID NO: 33,673 that is associated with an altered risk for autoantibody-positive autoimmune disease.

When the rejected claims are analyzed in light of the specification, the instant invention encompasses methods comprising the detection of a variety of nucleic acid sequences. The claims are drawn to a plurality of nucleic acids that encompass nucleotide content at position 101 of SEQ ID NO: 33673. Page 6 lines 9-15 of the specification indicates that a SNP can be a substitution of any nucleotide at a position, an insertion of any nucleotide at a position, or the deletion of the nucleotides content at a give position. Thus the claims encompass the detection of a variety of at least 9 different nucleotide sequences wherein the nucleic acid sequence is correlated with any altered risk for autoimmune disease. The nucleic acids of this genus have not been taught by the specification.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. The instant specification provides the sequence of SEQ ID NO: 36,673 wherein the nucleotide at position 101 is indicated to be polymorphic and can be either a C or a T, and provides an analysis indicating that the presence of a T is correlated with an increased risk of developing RF+ RA. The specification does not provide any other polymorphic content at position 101 of SEQ ID NO: 36,673 that is correlated with any altered risk for any autoimmune disease.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the specification does not

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provide any characteristics that would allow the identification of the broadly claimed SNP at position 101 of SEQ ID NO: 36,673 other than the C/T at the required position which would allow for the identification of an individual who has an altered risk for developing an autoantibody-positive autoimmune disease.

Applicants' attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In the instant application, because of the lack of any analysis regarding the broadly claimed SNP at position 101 of SEQ ID NO: 33,891 other than the particular C/T content at position 101, one of skill in the art cannot envision the detailed chemical structure of the nucleic acids with the required functionalities encompassed by the claimed methods, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that such nucleic acids are part of the invention and reference to a potential method for identification.

In conclusion, the limited information provided regarding the nucleic acids of the claimed methods is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a method for identification of an individual with an altered risk for developing an autoantibody-positive autoimmune disease by determining

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the presence of a SNP at position 101 of SEQ ID NO: 36,673 other than methods using the C/T SNP at position 101 of SEQ ID NO: 36,673.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

Response to Remarks

Applicants have traversed the rejection of claims under 35 USC 112 1st ¶ for lack of adequate written description. Applicants argue (p.9 of Remarks) that, as amended, the claims specify one SNP (hCV16021387, rs2476601) within SEQ ID NO: 36,673. This argument is not found to be persuasive. The rejected claims recite only 'a SNP at position 101 of SEQ ID NO: 36,673, where the specification teaches only the particular nucleotide content of either C or T at position 101 of the required SEQ ID NO. As such the claims as instantly presented encompass a genus of nucleotide sequences with additional substitutions, insertions, or a deletion at the indicated position, where the specification does not disclose such sequences and provides no analysis of which, if any, such sequences would have the required property of being indicative of an altered risk for developing an autoantibody-positive autoimmune disease.

The rejection as set forth is **MAINTIANED**.

Maintained Claim Rejection - 35 USC § 112 1st ¶ - Scope of Enablement

8. Claims 1 and 27-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification:

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While being enabling for:

A method for identifying a human individual who has an increased risk for developing positive autoantibody rheumatoid factor (RF+) rheumatoid arthritis (RA) comprising:

obtaining a biological sample from said individual wherein the biological sample comprises nucleic acids;

detecting the nucleotide content at position 101 of SEQ ID NO: 36,673 in said nucleic acids;

wherein, detecting the nucleotide T at position 101 of SEQ ID NO: 36,673 identifies the individual as having an increased risk for developing RF+ RA, and detecting the nucleotide C at position 101 of both alleles of SEQ ID NO: 36,673 identifies the individual as having a decreased risk for developing RF+ RA

does not reasonably provide enablement for methods comprising identification methods comprising correlating any other nucleotide content at position 101 of SEQ ID NO: 36,673 with any autoantibody-positive autoimmune disease other than RF+ RA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Nature of the invention and breadth of the claims

The claims of the instant application are drawn to methods for identifying an individual who has an altered risk for developing an autoantibody-positive autoimmune disease.

The claims encompass detecting any nucleotide content at position 101 of SEQ ID NO: 36,673. Relevant to claims 56-65, the claims encompass the detection of the presence of C at position 101 of SEQ ID NO: 36,673 as part of either a C/C (homozygous) genotype or C/T (heterozygous) genotype where either detection is

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indicative of a decreased risk of autoantibody-positive autoimmune disease including RF+ RA (claim 58).

The claims broadly encompass methods in which detection of a SNP is correlated with any altered risk (i.e. increased risk or decreased risk) of any autoantibody-positive autoimmune disease.

The nature of the inventions requires knowledge of an association between the broadly claimed nucleic acid content and altered risk of having any autoantibody-positive autoimmune disease.

Direction provided by the specification and working example

The instant specification teaches that an association study of a SNP and a specific disorder involves determining the presence or frequency of the SNP allele in biological samples from individuals with the disorder (i.e. cases) of interest and comparing the information to that of control individuals who do not have the disorder (p.7 ln.25).

The instant specification provides an example of an association study of the polymorphic content at position 101 of SEQ ID NO: 36,673, which may be either a C or a T, and is also identified as hCV16021387 and known in the art as rs2476601. The specification teaches that the frequency of the particular allele was analyzed in two (p.119 lns.6-20) patient populations: a Discovery Set (475 unrelated cases and 475 controls who were RF+); and a Replication Set (840 cases from 463 families and 926 controls). The specification further indicates that various strata (e.g. stratification by

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sex, age of RA onset, RF+, and number of high or low risk HLA epitopes (p.21)) of each population was also analyzed.

The specification teaches the specific association of the T allele (i.e. a T nucleotide at position 101 of SEQ ID NO: 36,673) with an increased risk of RA as the T allele is found at a significantly higher frequency in the case samples of the Discovery Set and the Replication Set (Table 6; p.121, Ins.21-27). It is noted that Table 6 designates the 'A' allele as associated with the increased risk of RA, and the specification indicates that nucleotide content may be described as the reverse complement of the nucleotide content at the position (e.g. p.19, Ins.13-19), thus the A allele of the reverse complement of SEQ ID NO: 36,673 is the T allele of SEQ ID NO: 36,673. The specification does not provide any genotype analysis, and as such it is possible only to conclude that the T allele in either the T/T or C/T genotype is indicative of increased risk of RF+-RA, and C/C genotype is indicative of decreased risk of RF+ RA. The analysis of the Discovery Set is an analysis of RF+ RA, because as stated in the specification all cases of the Discovery Set were RF+. While the instant specification provides that the T allele is indicative of increased risk for RA in the Replication Set, and specifically for the RF+ stratum, the instant specification provides no data for the RF- stratum of the replication set, nor any indication as to how many individuals in the Replication Set were either RF+ or RF-. Thus while the data of specification teaches an association of the T allele with RF+ RA, it is not clear from the specification if the T allele is associated with RF- RA.

The instant specification asserts that since autoimmune diseases share certain similar features that may be due to common genetic factors, SNPs associated with RA may also be used as makers for other autoimmune diseases (p.9, ln.1; p.121, ln.28). However, the instant specification provides no indication of any particular level of association of any SNP with any phenotype other than RA.

The instant specification provides only the association analysis of either C or T content at position 101 of SEQ ID NO: 36,673, and does not provide any analysis of any other polymorphic content at any other position of SEQ ID NO: 36,673.

State of the art, level of skill in the art, and level of unpredictability

While the state of the art and level of skill in the art with regard to the detection of a polymorphism in a known gene sequence is high, the level of unpredictability in associating any particular polymorphism with a phenotype is even higher. The level of unpredictability is demonstrated by the prior art, the post filing art, and the instant specification.

The prior art does not teach any association between any polymorphism in SEQ ID NO: 36,673 and altered risk for developing any autoimmune disease. And because the claims encompass the detection of any SNP at position 101 of SEQ ID NO: 36,673, it is relevant to point out the unpredictability in associating any particular SNP with a particular phenotypic trait. For example, Hacker et al teaches that they were unable to confirm an association between a gene mutation and ulcerative colitis in a case where prior studies suggested such a relationship would exist since the relationship had been identified in a different population (Gut, 1997, Vol. 40, pages 623-627).

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Because the claim encompass identifying an altered risk of any form of RA, it is relevant to point out that the instant specification does not particularly indicate an association between the nucleotide content of position 101 of SEQ ID NO: 36,673 and RF- RA. The post filing art of Harrison et al (2006) indicates that, in an analysis of the SNP identified as rs2476601, it was found that the presence of the T allele in an individual is associated with RF+ RA, but not associated with RF- RA (p.1010, left col., 1st ¶ of Results; Table 1; p.1011, left col., Key messages box). Similarly, Lee et al (2005) teach that the rs2476601 polymorphism is not associated with RF- RA (p.129 – Abstract; p.130, right col., Ins.5-15; Table 1), and Begovich et al (2004) indicate that the T allele of rs2476601 (p.331, left col., Ins.14-15) is not significantly associated with RF- RA (Table 3; p.333, right col., Ins.9-13). It is thus highly unpredictable as to whether or not the nucleotide content of position 101 of SEQ ID NO: 36,673 is reliably associated with increased risk of the RF- form of RA.

And while the claims broadly encompass identifying altered risk of any autoantibody-positive autoimmune disease, it is relevant to point out that the post-filing art of Criswell et al (2005) indicates that the rs2476601 SNP is not significantly associated with several autoimmune diseases, for example Graves disease or multiple sclerosis (p.567, left col., Ins.22-32; Table 5) where the 95% confidence interval (95% CI) of the odds ratio (OR) includes the value of 1.00 (Table 5). It is thus highly unpredictable which particular, if any, autoimmune diseases other than RF+ RA, are associated with the nucleotide content of position 101 of SEQ ID NO: 36,673. Additionally, the post-filing art of Ittah et al (2005) indicates the unpredictability of

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generically associating a particular nucleotide content with any autoantibody-positive autoimmune disease. Ittah et al teaches that the SNP of the instant elected invention (referred to in the reference as PTPN22 1858 C/T) shows no significant association with autoantibody patterns in the autoimmune disease primary Sjogren's syndrome (p.458, left col., Ins.4-7; Table 2). Further, the study of Myasthenia Gravis presented in the post-filing art of Vandiedonck et al (2006) indicates that the unpredictability in broadly associating the SNP of the Elected invention with any autoantibody-positive autoimmune disease (Table 2, p.406 – Discussion).

Quantity of experimentation required

A large and prohibitive amount of experimentation would have to be performed in order to make and use the claimed invention in the full scope of the claims. Such experimentation would include determining the association of any polymorphic content (any substitution, insertion, or deletion) at position 101 of SEQ ID NO: 36,673 with any altered risk (increased risk or decreased risk) of developing any autoantibody-positive autoimmune disease. This would involve large case:control studies in multiple human populations, and the analysis of different sequence variants and a large number of phenotypes that are considered autoantibody-positive autoimmune diseases. Even if such a large analysis were to be performed, there is no guarantee that one would find any significant associations beyond those specifically taught in the particular example of the instant specification.

Conclusion

Taking into consideration the factors outlined above, including the nature of the

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invention and breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the lack of guidance by the applicant and the few specific working examples, it is the conclusion that an undue amount of experimentation would be required to make and use the invention in the full scope of the claims.

Response to Remarks

9. Applicants have traversed the rejection of claims under 35 USC 112 1st ¶ for lack of full enablement. Initially Applicants argue (p.9 of Remarks) that the claims recite one specific SNP located within SEQ ID NO: 36,673. This is not persuasive because while the claims do recite a specific position (i.e. position 101) within a particular sequence (SEQ ID NO: 36,673), the claims (i.e. claims 1 and 27-45) are not limited to any specific detected nucleotide content (i.e. the claims encompass the detection of any substitution, insertion, or deletion at the indicated position) where the specification is enabled only for the C/T content at the indicated position. Additionally, claims 46-65 encompass the detection of any genotypes comprising the C allele (i.e. either the C/C homozygous or C/T heterozygous), where the specification supports only a conclusion of decreased risk of RF+ RA with the C/C homozygous genotype.

Applicants further argue that the instant claims are enabled with regard to the identification of risk of any autoantibody-positive autoimmune disease. Applicants point to the teachings of Criswell et al and Begovich et al which state that a particular PTNP22 is associated with several autoimmune disease that are autoantibody-positive (p.10 of Remarks). The argument is not persuasive because the claims (as addressed above in this response) encompass the detection of nucleotide content beyond the

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particular C/T content of the SNP analyzed in Criswell et al and Begovich et al.

Furthermore, the assertions of Criswell et al and Begovich et al are not evidence in support of the breadth of the claims where the claims require an association between a SNP and any autoantibody-positive autoimmune disease. Furthermore, the rejection as set forth provides the references of Ittah et al and Vandiedonck et al which provide evidence that the SNP of the elected invention is not in fact reliably associated with risk for any autoantibody-positive autoimmune disease.

The rejection as set forth is **MAINTAINED**.

Withdrawn Claim Rejections - 35 USC § 102

10. The rejection of claims 23 and 24 under 35 U.S.C. 102as being anticipated by GenBank GI 14970654 (17-July-2001) is withdrawn in light of the cancellation of claims 23 and 24.

Conclusion

11. No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Stephen Kapushoc
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NAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER